General

Title

Inflammatory bowel disease (IBD): percentage of patients aged 18 years and older with a diagnosis of IBD who have been managed by corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills that have been prescribed corticosteroid sparing therapy within the last 12 months.

Source(s)

American Gastroenterological Association (AGA). Inflammatory bowel disease (IBD): preventive care: corticosteroid sparing therapy. Bethesda (MD): American Gastroenterological Association (AGA); 2015 Dec 18. 7 p.

Measure Domain

Primary Measure Domain

Clinical Quality Measures: Process

Secondary Measure Domain

Does not apply to this measure

Brief Abstract

Description

This measure is used to assess the percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) who have been managed by corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills that have been prescribed corticosteroid sparing therapy within the last 12 months.

Rationale

Thirty to forty percent of patients with moderate to severe inflammatory bowel disease (IBD) have steroid dependent disease. That means that they are unable to taper off steroids without experiencing a flare up (Crohn's & Colitis Foundation of America [CCFA], 2009). A retrospective study examined whether the

treatment of Crohn's disease (CD) and ulcerative colitis (UC) with immunosuppressant medications was associated with an increased risk of death prior to anti-TNF (tumor necrosis factor) therapies. The authors found that patients with both CD and UC are at increased risk of death during periods of current corticosteroid use. In contrast, current treatment with thiopurines was not associated with an increased risk of death (Lewis et al., 2008). Similar findings were reached after an additional 5 years of follow-up in this patient population using multivariate logistic regression analyses which demonstrated a significant increase in mortality risk associated with chronic corticosteroid therapy, Hazard Ratio-2.14 (Lichtenstein et al., 2012).

Clinical Recommendation Statements:

Long-term treatment with corticosteroids is undesirable. Patients with chronic active corticosteroid-dependent disease (either CD or UC) should be treated with azathioprine (AZA) 2.0 to 3.0 mg/kg/day or 6-mercaptopurine (6-MP) 1.0 to 1.5 mg/kg/day in an effort to lower or preferably eliminate corticosteroid use. Infliximab is another option in this situation, as is combination infliximab/antimetabolite therapy (Lichtenstein et al., "Corticosteroids," 2006).

Individual patients with either CD or UC who experience a severe flare of disease requiring corticosteroid treatment or require retreatment during the year with another course of corticosteroids should be considered for initiation of therapy with AZA 2.0 to 3.0 mg/kg/day or 6-MP 1.1 to 1.5 mg/kg/day in an effort to avoid future corticosteroid use. Infliximab is another option in this situation, as is combination infliximab/antimetabolite therapy (Lichtenstein et al., "Corticosteroids," 2006).

Conventional corticosteroids are not efficacious in maintenance treatment of patients with CD or patients with UC (Lichtenstein et al., "Corticosteroids," 2006).

Corticosteroids should not be used to maintain remission (Travis et al., 2006).

Conventional corticosteroids should not be used as long-term agents to prevent relapse of CD. Budesonide at a dose of 6 mg/day reduces the time to relapse in ileal and/or right colonic disease, but does not provide significant maintenance benefits after 6 months. Azathioprine/6-mercaptopurine and methotrexate have demonstrable maintenance benefits after inductive therapy with corticosteroids (Lichtenstein et al., 2009).

This is the first report from the TREAT Registry, a large, prospective, observational research program designed to address the long term safety of medications, including infliximab, for the treatment of CD. After adjustment for confounding factors including disease severity and the use of other medications, the risk for serious infection or death with infliximab use was similar to that observed with the use of conventional immunomodulators, and was not higher than the overall incidence of serious infections among all CD patients.

The use of prednisone was a strong independent risk factor for both serious infection and death. Likewise, the use of narcotic analgesics also was associated with a significantly increased risk for serious infection (Lichtenstein et al., "Serious infections," 2006) Additionally, recently published American Gastroenterological Association (AGA) guidelines for Crohn's disease recommend using anti-TNF [tumor necrosis factor] alpha drugs to induce remission in patients with moderately severe Crohn's disease (Terdiman et al., 2013).

Evidence for Rationale

American Gastroenterological Association (AGA). Inflammatory bowel disease (IBD): preventive care: corticosteroid sparing therapy. Bethesda (MD): American Gastroenterological Association (AGA); 2015 Dec 18. 7 p.

Crohnâ€™s & Colitis Foundation of America (CCFA). Corticosteroids. [internet]. New York (NY): Crohnâ€™s & Colitis Foundation of America (CCFA); 2009 Jan 16.

Lewis JD, Gelfand JM, Troxel AB, Forde KA, Newcomb C, Kim H, Margolis DJ, Strom BL. Immunosuppressant medications and mortality in inflammatory bowel disease. Am J Gastroenterol. 2008 Jun;103(6):1428-35; quiz 1436. PubMed

Lichtenstein GR, Abreu MT, Cohen R, Tremaine W. American Gastroenterological Association Institute medical position statement on corticosteroids, immunomodulators, and infliximab in inflammatory bowel disease. Gastroenterology. 2006 Mar;130(3):935-9. PubMed

Lichtenstein GR, Feagan BG, Cohen RD, Salzberg BA, Diamond RH, Chen DM, Pritchard ML, Sandborn WJ. Serious infections and mortality in association with therapies for Crohn's disease: TREAT registry. Clin Gastroenterol Hepatol. 2006 May;4(5):621-30. PubMed

Lichtenstein GR, Feagan BG, Cohen RD, Salzberg BA, Diamond RH, Price S, Langholff W, Londhe A, Sandborn WJ. Serious infection and mortality in patients with Crohn's disease: more than 5 years of follow-up in the TREATâ„¢ registry. Am J Gastroenterol. 2012 Sep;107(9):1409-22. PubMed

Lichtenstein GR, Hanauer SB, Sandborn WJ, Practice Parameters Committee of American College of Gastroenterology. Management of Crohn's disease in adults. Am J Gastroenterol. 2009 Feb;104(2):465-83; quiz 464, 484. [270 references] PubMed

Terdiman JP, Gruss CB, Heidelbaugh JJ, Sultan S, Falck-Ytter YT, AGA Institute Clinical Practice and Quality Management Committee. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF-a biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. Gastroenterology. 2013 Dec;145(6):1459-63. [2 references] PubMed

Travis SP, Stange EF, LÃ©mann M, Oresland T, Chowers Y, Forbes A, D'Haens G, Kitis G, Cortot A, Prantera C, Marteau P, Colombel JF, Gionchetti P, Bouhnik Y, Tiret E, Kroesen J, Starlinger M, Mortensen NJ, European Crohn's and Colitis Organisation. European evidence based consensus on the diagnosis and management of Crohn's disease: current management. Gut. 2006 Mar;55 Suppl 1:i16-35. PubMed

Primary Health Components

Inflammatory bowel disease (IBD); corticosteroid sparing therapy; prednisone

Denominator Description

All patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) (see the related "Denominator Inclusions/Exclusions" field)

Numerator Description

Patients prescribed a corticosteroid sparing therapy (e.g., thiopurines, methotrexate, or biologic agents) (see the related "Numerator Inclusions/Exclusions" field)

Evidence Supporting the Measure

Type of Evidence Supporting the Criterion of Quality for the Measure

A clinical practice guideline or other peer-reviewed synthesis of the clinical research evidence

A formal consensus procedure, involving experts in relevant clinical, methodological, public health and organizational sciences

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

Additional Information Supporting Need for the Measure

Unspecified

Extent of Measure Testing

Unspecified

State of Use of the Measure

State of Use

Current routine use

Current Use

not defined yet

Application of the Measure in its Current Use

Measurement Setting

Ambulatory/Office-based Care

Professionals Involved in Delivery of Health Services

not defined yet

Least Aggregated Level of Services Delivery Addressed

Individual Clinicians or Public Health Professionals

Statement of Acceptable Minimum Sample Size

Specified

Target Population Age

Age greater than or equal to 18 years

Target Population Gender

Either male or female

National Strategy for Quality Improvement in Health Care

National Quality Strategy Aim

Better Care

National Quality Strategy Priority

Prevention and Treatment of Leading Causes of Mortality

Institute of Medicine (IOM) National Health Care Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Data Collection for the Measure

Case Finding Period

The reporting period (January 1 through December 31)

Denominator Sampling Frame

Patients associated with provider

Denominator (Index) Event or Characteristic

Clinical Condition

Encounter

Patient/Individual (Consumer) Characteristic

Denominator Time Window

not defined yet

Denominator Inclusions/Exclusions

Inclusions
All patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD)

Denominator Criteria (Eligible Cases):

Patients aged greater than or equal to 18 years on date of encounter

AND

Diagnosis for IBD (International Classification of Diseases, Tenth Revision, Clinical Modification [ICD-10-CM] codes): K50.00, K50.011, K50.012, K50.013, K50.014, K50.018, K50.019, K50.10, K50.111, K50.112, K50.113, K50.114, K50.118, K50.119, K50.80, K50.811, K50.812, K50.813, K50.814, K50.818, K50.819, K50.90, K50.911, K50.912, K50.913, K50.914, K50.918, K50.919, K51.00, K51.011, K51.012, K51.013, K51.014, K51.018, K51.019, K51.20, K51.211, K51.212, K51.213, K51.214, K51.218, K51.219, K51.30, K51.311, K51.312, K51.313, K51.314, K51.318, K51.319, K51.40, K51.411, K51.412, K51.413, K51.414, K51.418, K51.419, K51.50, K51.511, K51.512, K51.513, K51.514, K51.518, K51.519, K51.80, K51.811, K51.812, K51.813, K51.814, K51.818, K51.819, K51.90, K51.911, K51.912, K51.913, K51.914, K51.918, K51.919

AND

Patient encounter during the reporting period (refer to the original measure documentation for specific Current Procedural Terminology [CPT] codes)

AND

Patient who has received or is receiving corticosteroids* greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills within the last twelve months: G9467

**Corticosteroids*: Prednisone equivalents used expressly for the treatment of IBD and not for other indications (including premedication before anti-TNF [tumor necrosis factor] therapy, non-IBD indications) can be determined using the following: 1 mg of prednisone = 1 mg of prednisolone; 5 mg of cortisone; 4 mg of hydrocortisone; 0.8 mg of triamcinolone; 0.8 mg of methylprednisolone; 0.15 mg of dexamethasone; 0.15 mg of betamethasone.

Exclusions
None

Exclusions/Exceptions

not defined yet

Numerator Inclusions/Exclusions

Inclusions
Patients prescribed a corticosteroid sparing therapy (e.g., thiopurines, methotrexate, or biologic agents)

Exclusions

> Documentation of medical reason(s) for not treating with corticosteroid sparing therapy (e.g., benefits of continuing steroid therapy outweigh the risk of continuing steroid therapy or initiating steroid sparing therapy, patient is receiving the first course of corticosteroids for the treatment of inflammatory bowel disease [IBD])
> Documentation of patient reason(s) for not treating with corticosteroid sparing therapy (e.g., patient

refuses to initiate steroid sparing therapy)

Numerator Search Strategy

Fixed time period or point in time

Data Source

Administrative clinical data

Registry data

Type of Health State

Does not apply to this measure

Instruments Used and/or Associated with the Measure

Unspecified

Computation of the Measure

Measure Specifies Disaggregation

Does not apply to this measure

Scoring

Rate/Proportion

Interpretation of Score

Desired value is a higher score

Allowance for Patient or Population Factors

not defined yet

Standard of Comparison

not defined yet

Identifying Information

Original Title

Measure #270: inflammatory bowel disease (IBD): preventive care: corticosteroid sparing therapy.

Measure Collection Name

Inflammatory Bowel Disease

Submitter

American Gastroenterological Association - Medical Specialty Society

Developer

American Gastroenterological Association - Medical Specialty Society

Physician Consortium for Performance ImprovementÂ® - Clinical Specialty Collaboration

Funding Source(s)

Unspecified

Composition of the Group that Developed the Measure

Unspecified

Financial Disclosures/Other Potential Conflicts of Interest

Unspecified

Measure Initiative(s)

Physician Quality Reporting System

Adaptation

This measure was not adapted from another source.

Date of Most Current Version in NQMC

2015 Dec

Measure Maintenance

Unspecified

Date of Next Anticipated Revision

2017

Measure Status

This is the current release of the measure.

Measure Availability

Source not available electronically.

For more information, contact the American Gastroenterological Association (AGA) at 4930 Del Ray Avenue, Bethesda, MD 20814; Phone: 301-654-2055; Fax: 301-654-5920; E-mail: measures@gastro.org; Web site: www.gastro.org .

NQMC Status

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Copyright Statement

Production

Source(s)

American Gastroenterological Association (AGA). Inflammatory bowel disease (IBD): preventive care: corticosteroid sparing therapy. Bethesda (MD): American Gastroenterological Association (AGA); 2015 Dec 18. 7 p.

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